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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,196	08/02/2001	Irma H. Russo	13254-00012	6024

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[REDACTED] EXAMINER

YU, MISOOK

[REDACTED] ART UNIT      [REDACTED] PAPER NUMBER

1642

DATE MAILED: 09/10/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/868,196	RUSSO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 02 July 2003.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 45,54-65,70-78 and 80 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 45,54-65,70-78 and 80 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .	6) <input type="checkbox"/> Other: _____

## DETAILED ACTION

### ***Election/Restrictions***

Applicant's election without traverse of group III in Paper No.11 is acknowledged.

Claims 45, 54-65, 70-78, and 80 are pending and examined on merits.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 45, 54-58, 70, and 75 are rejected under 35 U.S.C. 102(b) as being anticipated by any one of Srivastava et al (1997, IDS AX, cited in ISR, Carcinogenesis, vol. 18, pages 1799-1808), Russo et al (1990, IDS AS, J. Natl, Cancer Inst. Vol. 82, pages 1286-1287), or Russo et al (1990, IDS AT, Br. J. Cancer, vol. 62, pages 2343-7).

Claim 45 (the base claim of the claimed invention) is drawn to method of treating or preventing mammary tumors with an active step of administering an effective amount of hCG to a host, wherein claim 54 further limits the mammary tumor to be clinically manifest, claim 55 further limits the tumor to be a primary tumor, claim 56 further limits the tumor to be a non-invasive carcinoma, claim 57 further limits the carcinoma to be a in situ or lobular carcinoma in situ, claim 58 further limits the tumor to be invasive carcinoma, claim 70 further limits the amount to be 100 to 20,000 IU per day, and claim 75 further limits hCG to be administered for several weeks.

Srivastava et al teach method of treating/preventing DMBA-induced mammary tumor (non invasive, invasive, carcinoma) by administering 100 IU hCG obtained from Sigma to a host for 40 days. Note Figs. 1 and, Materials and methods at page 1800, Table I and II at page 1801. Srivastava et al teach at page 1800, left column, line 10 that the hCG is obtained from Sigma.

Russo et al (IDS AS) teach method of treating/preventing DMBA-induced mammary tumor (non invasive, invasive, carcinoma) by administering 100 IU hCG. Note Fig. 1 and 2, and Table 1.

Russo et al (IDS AT) method of treating/preventing DMBA-induced mammary tumor (non invasive, invasive, carcinoma) by administering 100 IU hCG. Note Experimental protocol at page 2343, Tables I-III.

Claims 45, 54, 58, 60-64, and 70-72 are rejected under 35 U.S.C. **102(b)** as being anticipated by Grattarola (1976, Journal of the National Cancer Institute, vol. 56, pages 11-16).

Claim 45 (the base claim of the claimed invention) is drawn to method of treating or preventing mammary tumors with an active step of administering an effective amount of hCG to a host, wherein claims 54, 58, and 60 further limit the mammary tumor to be clinically manifest, to be invasive, and metastatic tumors respectively, claim 61 and 62 further limit the host to be pre-menopausal or post-menopausal woman, claims 63 and 64 further limit the therapy to be combined with other therapy, surgery or chemotherapy respectively, claims 70-72 further limits amount of hCG.

The Office treats the preamble language of the instant base claim as non-limiting, since the language does not result in manipulative difference in steps of claims. It is the Office's position that the instantly claimed breast treatment method is anticipated by Grattarola, who teaches the active step of instant method with the same amount of the active ingredient, i.e. method of administering 15,000 IU hCG to advanced breast cancer patients who are either pre-menopausal and post-menopausal, and had undergone surgery. Note abstract, page 11-12, Table 1. Note the amount used in the prior art is the same amount used in instant claims 70-72. Therefore, the method taught by Grattarola would inherently result in the purpose stated in the preamble of instant claim, thus anticipating instant claims. See Bristol-Myers Squibb Co. v. Ben Venue Laboratories Inc., 58 USPQ2d 1508 (CA FC 2001).

Claim 45, 70-72, and 77 are rejected under 35 U.S.C. **102(b)** as being anticipated by Saal et al, Fertil Steril. 1991 Aug;56(2):225-9 as evidenced by Russo et al (cited above, 1990, IDS AT).

The claims are interpreted as drawn to method of administering hCG to a host with the recited (claims 70-72) amounts of hCG subcutaneously (claim 77). It is the Office's position that Saal et al teach the instantly claimed method because the method of the prior art without manipulative difference in active steps would result in the purpose stated in the instant preamble, i.e. prevention of mammary tumor. Note the abstract. Russo et al teach giving hCG to a host results in prevention of mammary tumor.

Claim 45, and 70-77 are rejected under 35 U.S.C. 102(b) as being anticipated by Anapliotou et al, Fertil Steril. 1996 Aug;66(2):305-11, as evidenced by Russo et al (cited above, 1990, IDS AT).

The claims are interpreted as drawn to method of administering hCG to a host with the recited amounts in claims 70-72 of hCG with the recited schedule, duration, and route recited in claims 73-76. It is the Office's position that Anapliotou et al teach the instantly claimed method because the method of the prior art without manipulative difference in active steps would result in the purpose stated in the instant preamble, i.e. prevention of mammary tumor Note the abstract. Russo et al teach giving hCG to a host results in prevention of mammary tumor.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Srivastava et al (1997, IDS AX, cited in ISR, Carcinogenesis, vol. 18, pages 1799-1808), Russo et al (1990, IDS AS, J. Natl, Cancer Inst. Vol. 82, pages 1286-1287), or Russo et al (1990, IDS AT, Br. J. Cancer, vol. 62, pages 2343-7) as applied to claims 45 and 58 above, and further in view of Silverstein et al (1994, Cancer, vol. 73, pages 1673-7, abstract only).

The claim is interpreted as drawn to method of administering hCG to patient with tubular or lobular invasive breast mammary carcinoma. Any one of the primary references teaches hCG has protective effect against breast cancer and Silverstein et al teach that tubular or lobular invasive breast mammary carcinoma is also breast cancer and cancer staging is well known in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to select which patients has the specifically recited stage of breast cancer and administer hCG.

Claim 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Srivastava et al (1997, IDS AX, cited in ISR, Carcinogenesis, vol. 18, pages 1799-1808), Russo et al (1990, IDS AS, J. Natl, Cancer Inst. Vol. 82, pages 1286-1287), or Russo et al (1990, IDS AT, Br. J. Cancer, vol. 62, pages 2343-7) as applied to claim 45 above, and further in view of Mgbonyebi et al (1997, IDS AL).

The claim is drawn to method of administering the active ingredient to estrogen positive mammary tumor. Mgbonyebi et al (1997, IDS AL) teach hCG is effective in inhibition of estrogen positive breast cancer cells. Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to detect which breast cancer is estrogen positive and practice instantly claimed invention with reasonable expectation of success.

Claim 78 is rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Srivastava et al (1997, IDS AX, cited in ISR, Carcinogenesis, vol. 18, pages 1799-1808), Russo et al (1990, IDS AS, J. Natl, Cancer Inst. Vol. 82, pages 1286-1287), or Russo et al (1990, IDS AT, Br. J. Cancer, vol. 62, pages 2343-7) as applied to claim 45

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above, and further in view of any one of Platanias et al (J Biol Chem. 1998 Mar 6;273:5577-81), Oberg et al (1989, J Natl Cancer Inst., vol. 81, pages 531-5), Recchia et al (Clin Ter. 1998 May-Jun;149:203-8), or Robinson et al (1990, Breast Cancer Res. Treat., vol. 15, pages 95-101, <sup>9-4-03, 15</sup> abstract only)

The claim is interpreted as drawn to a method of administering Type I interferon in combination with hCG. Any of the references teaches that Type I interferon has anti-tumor activity. Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use Type I interferon known to have anti-tumor effect with reasonable expectation of success.

Claim 80 is rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Srivastava et al (1997, IDS AX, cited in ISR, Carcinogenesis, vol. 18, pages 1799-1808), Russo et al (1990, IDS AS, J. Natl. Cancer Inst. Vol. 82, pages 1286-1287), or Russo et al (1990, IDS AT, Br. J. Cancer, vol. 62, pages 2343-7) as applied to claim 45 above, and further in view of Sigma catalog (1995, page 263 only).

The claim is drawn to the method using recombinant hCG. The Sigma catalog says that the recombinant hCG is commercially available, therefore it is the Office's position that claim 80 is an obvious variation of the base claim and one in ordinary skill would have practiced the instantly claimed invention with reasonable expectation of success before the effective filing date of instant invention.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-

308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu  
August 28, 2003

*Mary E. Mosher*  
MARY E. MOSHER  
PRIMARY EXAMINER  
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